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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,534	04/15/2004	G. Ian Rowlandson	IT140825 (5024-00118)	8247

26753 7590 11/29/2006

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EXAMINER

HELLER, TAMMIE K

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/825,534	<b>Applicant(s)</b> ROWLANDSON, G. IAN	
	<b>Examiner</b> Tammie Heller	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7,9,10,12-15,17,18 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7,9,10,12-15,17,18 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The amendment filed on September 8, 2006 has been received and considered. By this amendment, claims 1, 3, 5, 7, 9, 12, 18, and 20 have been amended, claims 2, 4, 6, 8, 11, 16, and 19 have been cancelled, and claims 1, 3, 5, 7, 9, 10, 12-15, 17, 18, and 20 are now pending in the application.

### ***Response to Arguments***

2. Applicant's arguments with respect to claims 1, 3, 5, 7, 9, 10, 12-15, 18, and 20 have been considered but are moot in view of the new ground(s) of rejection.

3. Applicant's arguments filed September 8, 2006 regarding the rejection of claim 17 under 35 USC 102(e) as being anticipated by Lozier have been fully considered but they are not persuasive. Applicant argues that Lozier fails to disclose a single report that includes image data, image patterns, image correlations, image measurements, mathematical measurements, parameter values, ranges, recommended treatments, or a recommended follow up test. While the Examiner agrees with Applicant's assertion that Lozier fails to disclose a single report that includes information regarding image data, the Examiner contends that Lozier continues to read on claim 17. As currently written, claim 17 requires that the single report include at least one of "electrocardiogram data, an electrocardiogram pattern, an electrogram correlation, an electrogram measurement, image data, an image pattern, an image correlation, an image measurement, a mathematical measurement, a parameter value, and a range." As discussed at paragraph 15 of the Office Action of July 5, 2006, Lozier discloses including in a single

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report an electrogram measurement 203 (see Figure 2). Therefore, Lozier anticipates current claim 17.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 17 is rejected under 35 U.S.C. 102(e) as being anticipated by Lozier, previously cited. Regarding claim 17, Lozier discloses a system for identifying patients who may be at risk for sudden cardiac death. The method of Lozier includes the steps of acquiring patient data from a plurality of medical equipment databases (see paragraph 5, ln. 5-10) and analyzing the patient data to determine a sudden cardiac death risk score (see paragraph 13, ln. 10-14). Further, the invention of Lozier is directed towards a computer program which reports to the user data acquired from a plurality of medical devices which includes a physician identifier 208, a patient identifier 201, an electrogram measurement 203, and a diagnosis 205 (see Figure 2).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 5, 7, 9, 10, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Misczynski et al. (U.S. 2002/0188214, previously cited), herein Misczynski, in view of Lozier, previously cited. Regarding claims 1 and 12, Misczynski discloses a device and process for analyzing a medical condition of a patient that includes acquiring patient data, comparing the patient data to stored patterns to determine a measurement with an analysis mode, comparing the measurement to a range to determine a correlation with a decision support module, and diagnosing a sudden cardiac risk score (see Figure 1A). However, Misczynski discloses that the patient data is acquired in real time from sensor electrodes positioned on the patients body. Lozier discloses a system that assesses cardiac patients to evaluate their risk for sudden cardiac death. Lozier utilizes a plurality of medical equipment databases to acquire the patient data in order for the patient data to be accessible and able to be analyzed by physicians at different locations at different times (see paragraphs 5 and 11). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to acquire patient data from a plurality of medical equipment databases, as taught by Lozier, to carry out the invention of Misczynski in order to allow the system to be universally used by physicians at different locations at different times, thereby allowing the patient's risk of sudden cardiac death to be assessed by a plurality of physicians.
8. Regarding claim 5, Misczynski discloses that the patient data includes electrocardiogram data (see paragraph 13).

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9. Regarding claim 7, Mischynski discloses that the patient data includes a mathematical measurement based on a parameter value (see paragraph 19).

10. Regarding claim 9, Mischynski discloses that diagnosing the sudden cardiac death risk score is based on an ECG correlation or a mathematical correlation (see paragraph 19 and 20).

11. Regarding claim 10 and 13, Mischynski discloses sending the electrogram data or the sudden cardiac death risk score to a remote storage and processing device (see Figure 1A).

12. Regarding claims 14 and 15, Mischynski discloses integrated circuit 220 and 221 that includes medical information analyzer 230 and abnormality identifier 260 that act as a pattern recognition module and a mathematically relationship module to analyze the ECG data obtained (see Figures 1, 3, and 4 and paragraph 19).

13. Claims 3 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mischynski in view of Lozier as applied to claims 1, 5, 7, 9, 10, and 12-15 above, and further in view of Guerrero, cited in previous Office Action. Mischynski in view of Lozier discloses the invention essentially as claimed, but fails to disclose the use of patient image data to produce the sudden cardiac death score. Guerrero discloses a method of analyzing biological signals via a computerized visual analysis technique, CVAT. Guerrero further discloses that CVAT, in conjunction with Holter monitoring, is an effective method of detecting an increased risk of arrhythmia and sudden cardiac death (see col. 24, ln. 54-56). Therefore, it would have been obvious to one having ordinary

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skill in the art at the time of the invention to utilize the CVAT method of Guerrero in conjunction with the invention of Mischzynski in view of Lozier in order to provide a method of detecting sudden cardiac death, and thus provide a more accurate sudden cardiac death risk score.

14. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mischzynski in view of Guerrero. Mischzynski discloses a device and process for analyzing a medical condition of a patient that includes an acquisition module operable to acquire ECG data, an analysis module operable to calculate a plurality of measurements based on the ECG data, a decision support module that analyzes the plurality of measurements and determines a level of heart disease, and a diagnosis module to generate a sudden cardiac death score based on the level of heart disease (see Figure 1A). However, Mischzynski fails to disclose acquiring image data that can be utilized by the analysis module. Guerrero discloses a method of analyzing biological signals via a computerized visual analysis technique, CVAT. Guerrero further discloses that CVAT, in conjunction with Holter monitoring, is an effective method of detecting an increased risk of arrhythmia and sudden cardiac death (see col. 24, ln. 54-56). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize the CVAT method of Guerrero in conjunction with the invention of Mischzynski in order to provide a method of detecting sudden cardiac death, and thus provide a more accurate sudden cardiac death risk score.

**Conclusion**

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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